

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Southern Research Institute	052011407	10/02/02	730	50(3)	28(696)	532.4	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601905	09/26/01	729	50(3)	31(686)	526.0	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601505	09/05/01	729	50(3)	31(692)	507.8	Water disinfection byproducts (Dibromoacetonitrile)
Female							
Southern Research Institute	052011407	10/02/02	735	50(5)	33(700)	351.2	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601905	09/26/01	731	50(5)	34(688)	357.3	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601505	09/05/01	734	50(5)	29(689)	337.6	Water disinfection byproducts (Dibromoacetonitrile)

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		Male			Female		
#All Organs:							
Benign Tumors							
		49/50 (98%)	50/50 (100%)	50/50 (100%)	47/50 (94%)	49/50 (98%)	44/50 (88%)
Overall Incidence	Total	149/150 (99.33%)	Mean 99.33%	SD 1.15%	Total 140/150 (93.33%)	Mean 93.33%	SD 5.03%
.....							
#All Organs:							
Malignant Tumors							
		29/50 (58%)	27/50 (54%)	27/50 (54%)	20/50 (40%)	18/50 (36%)	20/50 (40%)
Overall Incidence	Total	83/150 (55.33%)	Mean 55.33%	SD 2.31%	Total 58/150 (38.67%)	Mean 38.67%	SD 2.31%
.....							
#All Organs:							
Malignant and Benign Tumors							
		50/50 (100%)	50/50 (100%)	50/50 (100%)	49/50 (98%)	49/50 (98%)	48/50 (96%)
Overall Incidence	Total	150/150 (100%)	Mean 100%	SD 0%	Total 146/150 (97.33%)	Mean 97.33%	SD 1.15%
.....							
#All Organs:							
Hemangioma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#All Organs:							
Hemangiosarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....							
#All Organs:							
Hemangiosarcoma or Hemangioma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

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		Male			Female		
#All Organs:							
Histiocytic Sarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#All Organs:							
Leukemia: Erythrocytic							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated							
		26/50 (52%)	21/50 (42%)	21/50 (42%)	8/50 (16%)	15/50 (30%)	14/50 (28%)
Overall Incidence	Total	68/150 (45.33%)	Mean 45.33%	SD 5.77%	Total	37/150 (24.67%)	Mean 24.67% SD 7.57%
.....							
#All Organs:							
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#All Organs:							
Mesothelioma: Benign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#All Organs:							
Mesothelioma: Benign, Malignant, NOS							
		2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0% SD 0%

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		Male				Female			
#All Organs:									
Mesothelioma: Malignant									
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#All Organs:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Adrenal Cortex:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Adrenal Cortex:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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		Male				Female			
*Adrenal Medulla: Ganglioneuroma									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/147 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla: Hemangioma									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/147 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla: Pheochromocytoma Benign									
		6/49 (12%)	9/50 (18%)	10/50 (20%)		2/49 (4%)	2/49 (4%)	1/49 (2%)	
Overall Incidence	Total	25/149 (16.78%)	Mean 16.75%	SD 4.03%	Total	5/147 (3.4%)	Mean 3.4%	SD 1.18%	
.....									
*Adrenal Medulla: Pheochromocytoma Complex									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/147 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla: Pheochromocytoma Malignant									
		1/49 (2%)	1/50 (2%)	0/50 (0%)		1/49 (2%)	2/49 (4%)	0/49 (0%)	
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	3/147 (2.04%)	Mean 2.04%	SD 2.04%	
.....									
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS									
		7/49 (14%)	10/50 (20%)	10/50 (20%)		3/49 (6%)	4/49 (8%)	1/49 (2%)	
Overall Incidence	Total	27/149 (18.12%)	Mean 18.1%	SD 3.3%	Total	8/147 (5.44%)	Mean 5.44%	SD 3.12%	

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		Male				Female					
#Bone:											
Chondrosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
#Bone:											
Chondrosarcoma or Chondroma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
#Bone:											
Chordoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Bone:											
Osteoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Bone:											
Osteosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
#Bone:											
Osteosarcoma or Osteoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	

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		Male				Female					
*Brain:											
Astrocytoma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Ependymoma Benign											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Ependymoma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Glioma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Granular Cell Tumor Benign											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Medulloblastoma Mal											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

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		Male				Female					
*Brain:											
Oligodendroglioma Benign											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Oligodendroglioma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Oligodendroglioma, Glioma, or Astrocytoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Osteosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Brain:											
Schwannoma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Clitoral/Preputial Gland:											
Adenoma											
		4/50	(8%)	4/50	(8%)	1/48	(2%)	2/50	(4%)	17/50	(34%)
Overall Incidence	Total	9/148	(6.08%)	Mean 6.03%	SD 3.42%	Total	24/150	(16%)	Mean 16%	SD 15.87%	

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		Male			Female		
*Clitoral/Preputial Gland: Carcinoma							
Overall Incidence	Total	1/50 (2%) 3/148 (2.03%)	2/50 (4%) Mean 2%	0/48 (0%) SD 2%	8/50 (16%) 9/150 (6%)	0/50 (0%) Mean 6%	1/50 (2%) SD 8.72%
*Clitoral/Preputial Gland: Carcinoma or Adenoma							
Overall Incidence	Total	4/50 (8%) 10/148 (6.76%)	5/50 (10%) Mean 6.69%	1/48 (2%) SD 4.12%	10/50 (20%) 33/150 (22%)	17/50 (34%) Mean 22%	6/50 (12%) SD 11.14%
*Clitoral/Preputial Gland: Fibrosarcoma							
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Sarcoma							
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Ear: Neural Crest Tumor							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Fibrosarcoma							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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		Male			Female			
#Esophagus:								
Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Eye:								
Melanoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Eye:								
Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Harderian Gland:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Harderian Gland:								
Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Heart:								
Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

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#: Denominator is number of animals necropsied

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		Male			Female		
*Heart:							
Schwannoma Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....							
#Intestine Large: Colon/Rectum:							
Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#Intestine Large: Colon/Rectum:							
Carcinoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....							
#Intestine Large: Colon/Rectum:							
Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....							
#Intestine Large: Colon/Rectum:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#Intestine Small: Duodenum:							
Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female			
#Intestine Small: Duodenum:								
Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Intestine Small: Ileum:								
Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Intestine Small: Jejunum:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Intestine Small: Jejunum:								
Granular Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Intestine Small: Jejunum:								
Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Intestine Small: Jejunum:								
Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male				Female					
#Intestine Small: Site Unspecified: Adenoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Carcinoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Carcinoma or Adenoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Intestine Small: Site Unspecified: Leiomyoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
#Intestine Small: Site Unspecified: Leiomyosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female			
*Islets, Pancreatic:								
Adenoma								
		4/50 (8%)	3/50 (6%)	5/49 (10%)	2/50 (4%)	3/49 (6%)	1/50 (2%)	
Overall Incidence	Total	12/149 (8.05%)	Mean 8.07%	SD 2.1%	Total	6/149 (4.03%)	Mean 4.04%	SD 2.06%
.....								
*Islets, Pancreatic:								
Carcinoma								
		0/50 (0%)	2/50 (4%)	1/49 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	3/149 (2.01%)	Mean 2.01%	SD 2%	Total	0/149 (0%)	Mean 0%	SD 0%
.....								
*Islets, Pancreatic:								
Carcinoma or Adenoma								
		4/50 (8%)	5/50 (10%)	6/49 (12%)	2/50 (4%)	3/49 (6%)	1/50 (2%)	
Overall Incidence	Total	15/149 (10.07%)	Mean 10.08%	SD 2.12%	Total	6/149 (4.03%)	Mean 4.04%	SD 2.06%
.....								
*Kidney: Pelvis and Transitional Epithelium:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Kidney: Pelvis and Transitional Epithelium:								
Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Kidney: Pelvis and Transitional Epithelium:								
Papilloma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
*Kidney: Renal Tubule: Adenoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
*Kidney: Renal Tubule: Carcinoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
*Kidney: Renal Tubule: Hemangiosarcoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Lipoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Kidney: Renal Tubule: Mesenchymal Tumor Benign							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
*Kidney: Renal Tubule:							
 Mesenchymal Tumor Malignant							
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/149 (0%)	Mean 0%	SD 0%	0/150 (0%)	Mean 0%	SD 0%
.....							
*Kidney: Renal Tubule:							
 Nephroblastoma							
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/149 (0%)	Mean 0%	SD 0%	0/150 (0%)	Mean 0%	SD 0%
.....							
*Kidney: Renal Tubule:							
 Sarcoma							
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/149 (0%)	Mean 0%	SD 0%	0/150 (0%)	Mean 0%	SD 0%
.....							
*Liver:							
 Cholangioma							
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	0/150 (0%)	Mean 0%	SD 0%
.....							
*Liver:							
 Hemangiosarcoma							
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/150 (0%)	Mean 0%	SD 0%	0/150 (0%)	Mean 0%	SD 0%
.....							
*Liver:							
 Hepatocellular Adenoma							
Overall Incidence	Total	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		2/150 (1.33%)	Mean 1.33%	SD 2.31%	1/150 (0.67%)	Mean 0.67%	SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male				Female			
*Liver:									
Hepatocellular Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocellular Carcinoma or Hepatocellular Adenoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Liver:									
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
*Liver:									
Ito Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Alveolar/Bronchiolar Adenoma									
		4/50 (8%)	2/50 (4%)	3/50 (6%)		4/50 (8%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	9/150 (6%)	Mean 6%	SD 2%	Total	6/150 (4%)	Mean 4%	SD 3.46%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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		Male				Female			
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		4/50 (8%)	3/50 (6%)	4/50 (8%)		4/50 (8%)	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 1.15%	Total	6/150 (4%)	Mean 4%	SD 3.46%	
.....									
*Lung:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female			
#Mammary Gland:								
Adenolipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Mammary Gland:								
Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
.....								
#Mammary Gland:								
Carcinoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%
.....								
#Mammary Gland:								
Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%
.....								
#Mammary Gland:								
Fibroadenoma								
		2/50 (4%)	3/50 (6%)	6/50 (12%)	37/50 (74%)	43/50 (86%)	31/50 (62%)	
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 4.16%	Total	111/150 (74%)	Mean 74%	SD 12%
.....								
#Mammary Gland:								
Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
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		Male			Female		
#Mammary Gland:							
Fibroma, Fibroadenoma or Adenoma							
		2/50 (4%)	3/50 (6%)	6/50 (12%)	37/50 (74%)	43/50 (86%)	31/50 (62%)
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 4.16%	Total	111/150 (74%)	Mean 74% SD 12%
.....							
#Mammary Gland:							
Fibroma, Fibroadenoma, Carcinoma, or Adenoma							
		3/50 (6%)	3/50 (6%)	6/50 (12%)	37/50 (74%)	43/50 (86%)	31/50 (62%)
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 3.46%	Total	111/150 (74%)	Mean 74% SD 12%
.....							
#Mesentery:							
Fibrous Histiocytoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Mesentery:							
Hemangiosarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Mesentery:							
Lipoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Mesentery:							
Schwannoma Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male				Female					
*Nose:											
Adenoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Nose:											
Chondroma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
*Nose:											
Squamous Cell Carcinoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Papilloma Squamous or Papilloma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	3/150	(2%)	Mean 2%	SD 0%	
.....											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Squamous Cell Carcinoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	3/150	(2%)	Mean 2%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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		Male				Female					
#Oral Mucosa:											
Squamous Cell Carcinoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Oral Mucosa:											
Squamous Cell Papilloma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67%	SD 1.15%	
.....											
*Ovary:											
Cystadenoma											
						0/49	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/149	(0%)	Mean 0%	SD 0%	
.....											
*Ovary:											
Granulosa Cell Tumor Benign											
						0/49	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/149	(0%)	Mean 0%	SD 0%	
.....											
*Ovary:											
Granulosa Cell Tumor Malignant											
						0/49	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/149	(0%)	Mean 0%	SD 0%	
.....											
*Ovary:											
Granulosa Cell Tumor: Benign, Malignant, NOS											
						0/49	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/149	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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					Male						Female	
*Ovary:												
Granulosa-Theca Tumor Benign												
						0/49	(0%)		0/50	(0%)	1/50	(2%)
Overall Incidence					Total	1/149	(0.67%)		Mean	0.67%	SD	1.15%
.....												
*Ovary:												
Granulosa-Theca Tumor Malignant												
						0/49	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence					Total	0/149	(0%)		Mean	0%	SD	0%
.....												
*Ovary:												
Tubulostromal Adenoma												
						0/49	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence					Total	0/149	(0%)		Mean	0%	SD	0%
.....												
*Pancreas:												
Adenoma												
						1/50	(2%)	2/50	(4%)	1/49	(2%)	
Overall Incidence	Total	4/149	(2.68%)	Mean	2.68%	SD	1.14%	Total	0/50	(0%)	0/50	(0%)
						0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%
						0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%
.....												
*Pancreas:												
Carcinoma												
						0/50	(0%)	0/50	(0%)	0/49	(0%)	
Overall Incidence	Total	0/149	(0%)	Mean	0%	SD	0%	Total	0/50	(0%)	0/50	(0%)
						0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%
.....												
*Pancreas:												
Carcinoma or Adenoma												
						1/50	(2%)	2/50	(4%)	1/49	(2%)	
Overall Incidence	Total	4/149	(2.68%)	Mean	2.68%	SD	1.14%	Total	0/50	(0%)	0/50	(0%)
						0/50	(0%)		0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female			
*Pancreas:								
Mixed Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Pancreas:								
Mixed Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
*Parathyroid Gland:								
Adenoma								
		0/46 (0%)	0/44 (0%)	1/46 (2%)	0/46 (0%)	0/42 (0%)	0/42 (0%)	
Overall Incidence	Total	1/136 (0.74%)	Mean 0.72%	SD 1.26%	Total	0/130 (0%)	Mean 0%	SD 0%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Adenoma								
		16/50 (32%)	23/48 (48%)	24/50 (48%)	28/50 (56%)	28/50 (56%)	27/49 (55%)	
Overall Incidence	Total	63/148 (42.57%)	Mean 42.64%	SD 9.21%	Total	83/149 (55.7%)	Mean 55.7%	SD 0.52%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Carcinoma								
		0/50 (0%)	0/48 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%
.....								
*Pituitary Gland: Pars Distalis or Unspecified Site:								
Carcinoma or Adenoma								
		16/50 (32%)	23/48 (48%)	24/50 (48%)	30/50 (60%)	28/50 (56%)	27/49 (55%)	
Overall Incidence	Total	63/148 (42.57%)	Mean 42.64%	SD 9.21%	Total	85/149 (57.05%)	Mean 57.03%	SD 2.61%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
*Pituitary Gland: Pars Distalis or Unspecified Site:							
Ganglioneuroma							
Overall Incidence	Total	0/50 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%
							SD 0%
*Pituitary Gland: Pars Intermedia:							
Adenoma							
Overall Incidence	Total	0/50 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%
							SD 0%
*Pituitary Gland: Pars Intermedia:							
Carcinoma or Adenoma							
Overall Incidence	Total	0/50 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%
							SD 0%
*Pituitary Gland: Pars Nervosa:							
Craniopharyngioma							
Overall Incidence	Total	0/50 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%
							SD 0%
*Prostate:							
Adenoma							
Overall Incidence	Total	2/50 (4%)	0/50 (0%)	0/49 (0%)			
		2/149 (1.34%)	Mean 1.33%	SD 2.31%			
*Prostate:							
Carcinoma or Adenoma							
Overall Incidence	Total	2/50 (4%)	0/50 (0%)	0/49 (0%)			
		2/149 (1.34%)	Mean 1.33%	SD 2.31%			

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
*Salivary Glands:							
 Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Salivary Glands:							
 Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Salivary Glands:							
 Sarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Salivary Glands:							
 Schwannoma Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Seminal Vesicle:							
 Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%			
.....							
#Skeletal Muscle:							
 Fibrous Histiocytoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male				Female					
#Skeletal Muscle:											
Hemangiosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Skeletal Muscle:											
Rhabdomyosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Skeletal Muscle:											
Rhabdomyosarcoma or Rhabdomyoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Basal Cell Adenoma											
		2/50	(4%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	4/150	(2.67%)	Mean 2.67%	SD 2.31%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Basal Cell Adenoma or Basosquamous Tumor Benign											
		2/50	(4%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	4/150	(2.67%)	Mean 2.67%	SD 2.31%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Skin:											
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma											
		2/50	(4%)	3/50	(6%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	7/150	(4.67%)	Mean 4.67%	SD 1.15%	Total	0/150	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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		Male			Female		
#Skin:							
Basal Cell Carcinoma							
		0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)							
		0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma							
		2/50 (4%)	3/50 (6%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	9/150 (6%)	Mean 6%	SD 2%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma							
		5/50 (10%)	6/50 (12%)	11/50 (22%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	22/150 (14.67%)	Mean 14.67%	SD 6.43%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Skin:							
Fibroma							
		8/50 (16%)	7/50 (14%)	8/50 (16%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	23/150 (15.33%)	Mean 15.33%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%
.....							
#Skin:							
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma							
		11/50 (22%)	8/50 (16%)	9/50 (18%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 3.06%	Total	3/150 (2%)	Mean 2% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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		Male			Female			
#Skin:								
Fibrosarcoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma								
		3/50 (6%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....								
#Skin:								
Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangioma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
.....								
#Skin:								
Keratoacanthoma								
		2/50 (4%)	1/50 (2%)	6/50 (12%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	9/150 (6%)	Mean 6%	SD 5.29%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
#Skin:							
Lipoma							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
						SD 0%	
.....							
#Skin:							
Liposarcoma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
						SD 0%	
.....							
#Skin:							
Neural Crest Tumor							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%
						SD 0%	
.....							
#Skin:							
Neural Crest Tumor, Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
						SD 0%	
.....							
#Skin:							
Neurofibroma or Schwannoma benign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
						SD 0%	
.....							
#Skin:							
Neurofibrosarcoma or Schwannoma (malignant or NOS)							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
						SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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		Male				Female			
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Sarcoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Schwannoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 03/20/2010

		Male			Female		
#Skin:							
Squamous Cell Papilloma							
		1/50 (2%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Squamous Cell Papilloma or Papilloma							
		1/50 (2%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin:							
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma							
		4/50 (8%)	4/50 (8%)	7/50 (14%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	15/150 (10%)	Mean 10%	SD 3.46%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Skin:							
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma							
		3/50 (6%)	4/50 (8%)	7/50 (14%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 4.16%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%
.....							
#Skin:							
Trichoepithelioma							
		0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 3.46%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Skin: Sebaceous Gland:							
Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
#Skin: Sebaceous Gland:							
Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 1/150 (0.67%)	Mean 0.67%	SD 1.15%
.....							
#Spinal Cord:							
Astrocytoma Benign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#Spinal Cord:							
Astrocytoma Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
#Spinal Cord:							
Glioma Malignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
*Spleen:							
Fibrosarcoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%
.....							
*Spleen:							
Fibrous Histiocytoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total 0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 03/20/2010

		Male			Female		
*Spleen:							
Hemangiosarcoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Spleen:							
Leiomyosarcoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Spleen:							
Sarcoma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Forestomach:							
Leiomyosarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Forestomach:							
Squamous Cell Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Forestomach:							
Squamous Cell Carcinoma or Papilloma Squamous							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
#Stomach, Forestomach:							
Squamous Cell Papilloma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Glandular:							
Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Glandular:							
Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Glandular:							
Lipoma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
#Stomach, Glandular:							
Sarcoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%
.....							
*Testes:							
Adenoma							
		48/50 (96%)	46/50 (92%)	49/50 (98%)			
Overall Incidence	Total	143/150 (95.33%)	Mean 95.33%	SD 3.06%			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
*Testes:							
Hemangioma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%			
.....							
*Thymus:							
Thymoma Benign							
		0/48 (0%)	0/49 (0%)	0/43 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/140 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%
						SD 0%	
.....							
*Thymus:							
Thymoma Malignant							
		0/48 (0%)	0/49 (0%)	0/43 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/140 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%
						SD 0%	
.....							
*Thymus:							
Thymoma NOS							
		0/48 (0%)	0/49 (0%)	0/43 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/140 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%
						SD 0%	
.....							
*Thymus:							
Thymoma: Benign, Malignant, NOS							
		0/48 (0%)	0/49 (0%)	0/43 (0%)	0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/140 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%
						SD 0%	
.....							
*Thyroid Gland: C-Cell:							
Adenoma							
		5/50 (10%)	3/50 (6%)	10/49 (20%)	8/50 (16%)	6/49 (12%)	6/46 (13%)
Overall Incidence	Total	18/149 (12.08%)	Mean 12.14%	SD 7.44%	Total	20/145 (13.79%)	Mean 13.76%
						SD 1.98%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male			Female		
*Thyroid Gland: C-Cell: Carcinoma							
		1/50 (2%)	1/50 (2%)	1/49 (2%)	2/50 (4%)	1/49 (2%)	0/46 (0%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2.01%	SD 0.02%	Total	3/145 (2.07%)	Mean 2.01% SD 2%
.....							
*Thyroid Gland: C-Cell: Carcinoma or Adenoma							
		6/50 (12%)	4/50 (8%)	11/49 (22%)	10/50 (20%)	7/49 (14%)	6/46 (13%)
Overall Incidence	Total	21/149 (14.09%)	Mean 14.15%	SD 7.46%	Total	23/145 (15.86%)	Mean 15.78% SD 3.71%
.....							
*Thyroid Gland: Follicular Cell: Adenoma							
		0/50 (0%)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	1/46 (2%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	1/145 (0.69%)	Mean 0.72% SD 1.26%
.....							
*Thyroid Gland: Follicular Cell: Carcinoma							
		0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/145 (0%)	Mean 0% SD 0%
.....							
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma							
		0/50 (0%)	3/50 (6%)	0/49 (0%)	0/50 (0%)	0/49 (0%)	1/46 (2%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2%	SD 3.46%	Total	1/145 (0.69%)	Mean 0.72% SD 1.26%
.....							
#Tissue NOS: Lipoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 03/20/2010

		Male				Female					
#Tissue NOS:											
Paraganglioma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Tongue:											
Squamous Cell Carcinoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Tongue:											
Squamous Cell Carcinoma or Papilloma Squamous											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%	
.....											
#Tongue:											
Squamous Cell Papilloma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	2/150	(1.33%)	Mean 1.33%	SD 1.15%	
.....											
#Tooth:											
Adamantinoma Malignant											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
.....											
#Tooth:											
Odontoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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		Male				Female			
*Urinary Bladder: Carcinoma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder: Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
.....									
#Uterus: Adenoma									
						1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total				Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Uterus: Carcinoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total				Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 03/20/2010

	Male	Female
#Uterus: Deciduoma Benign		
Overall Incidence	Total 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Hemangioma		
Overall Incidence	Total 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Hemangiosarcoma		
Overall Incidence	Total 0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67% SD 1.15%
#Uterus: Leiomyosarcoma		
Overall Incidence	Total 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Polyp Stromal		
Overall Incidence	Total 10/50 (20%) 32/150 (21.33%)	9/50 (18%) Mean 21.33% SD 4.16%
#Uterus: Sarcoma		
Overall Incidence	Total 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 03/20/2010

		Male			Female		
#Uterus:							
Sarcoma Stromal							
			0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)		Mean 0%		SD 0%
.....							
#Uterus:							
Sarcoma Stromal or Polyp Stromal							
			10/50 (20%)		9/50 (18%)		13/50 (26%)
Overall Incidence		Total	32/150 (21.33%)		Mean 21.33%		SD 4.16%
.....							
#Uterus:							
Schwannoma Malignant							
			0/50 (0%)		0/50 (0%)		1/50 (2%)
Overall Incidence		Total	1/150 (0.67%)		Mean 0.67%		SD 1.15%
.....							
#Vagina:							
Polyp							
			0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)		Mean 0%		SD 0%
.....							
#Vagina:							
Sarcoma							
			0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)		Mean 0%		SD 0%
.....							
#Zymbal's Gland:							
Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%
						SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 03/20/2010

		Male				Female								
#Zymbal's Gland:														
Carcinoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%
.....														
#Zymbal's Gland:														
Carcinoma or Adenoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)			
Overall Incidence	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%
.....														

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied